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09/500,555	02/09/00	STUELPNAGEL J	A-67616-1/DJ

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/500,555	Applicant(s) STUELPNAGEL ET AL.	
	Examiner BJ Forman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 28-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 & 18-27, drawn to an array and method of making the array, classified in class 435, subclass 287.8.

II. Claims 13-17, drawn to a composition comprising a computer readable memory, classified in class 711, subclass 111

IV. Claims 28-31, drawn to a method for comparing data images, classified in class 700, subclass 91.

V. Claims 32-37, drawn to a method for decoding a random array, classified in class 422 subclass 82.05.

VI. Claim38-43, drawn to a method of determining the presence of a target analyte, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product i.e. the array composition of Invention I can be used to synthesize nucleic acids.

3. During a telephone conversation with David Foster on 16 April 2001 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12 & 18-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims

13-17 & 28-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-12 and 18-27 are under prosecution.

Claim Objections

5. Claim 1 is objected to because of the following informalities: the claim improperly recites "and" at the end of step a) and a semi-colon at the end of step c). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3. 19 & 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 19 & 20 are indefinite in the recitations "such that" and "can be" because it is unclear whether the recitations are method steps of elucidation or characteristics of the optical signature. It is suggested that the claims be amended to clarify e.g. replace "such that.....elucidated" with "for identification and elucidation of the bioactive agent".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-10 & 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (U.S. Patent No. 6,023,540, filed 14 March 1997) in view of Augenlicht, L. (U.S. Patent No. 4,981,783, filed 16 April 1986).

Regarding Claim 1, Walt et al. teach an array composition comprising: a substrate with a surface comprising discrete sites; and a population of microspheres comprising at least a first and a second subpopulation wherein each subpopulation comprises a bioactive agent (Column 8, lines 1-11) wherein said microspheres are distributed on said surface (Column 4, lines 4-14) but they do not teach the composition comprises at least one fiducial. However, Augenlicht teaches a similar array composition comprising a substrate comprising discrete sites; a population of bioactive agents comprising at least a first and second subpopulation wherein said agents are distributed on said surface; and at least one fiducial (Column 7, lines 18-35) wherein bioagents are identified relative to the position of the fiducials (Column 8, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the surface of Walt et al. to further comprise at least one fiducial for the expected benefit of facilitating analysis and identification of the bioagents by identifying their position on the substrate relative to the fiducial as taught by Augenlicht (Column 7, lines 33-35).

Regarding Claim 2, Walt et al. teach the array wherein each subpopulation comprises a unique optical signature (Column 4, lines 9-14).

Regarding Claim 3, Walt et al. teach the array wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated (Column 10, lines 37-60).

Regarding Claim 4, Walt et al. teach the array wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach a fiducial fiber. However, Augenlicht teaches the similar array comprising fiducials wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of bioagents of interest by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify substrate consisting of a fiber optic bundle of Walt et al. to include a fiducial fiber as a marker for the expected benefits of fiducial markers as taught by Augenlicht i.e. the markers facilitate analysis and identification of the bioagents by their position relative to the fiducial (Column 7, lines 33-35).

Regarding Claim 5, Walt et al. teach the array wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach said array comprises at least three non-linear fiducials. However, Augenlicht teaches the similar array comprising at least three non-linear fiducials (Fig. 1) wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of the bioagents by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26).

Regarding Claim 6, Augenlicht teach the similar array comprising at least one fiducial wherein the position of the fiducial on the substrate facilitates analysis and identification of the bioagents by identifying their position relative to the fiducial (Column 7, lines 33-35) but they do not teach that one fiducial has a different shape from the others. However, it would have been obvious to one skilled in the art to modify fiducials of Augenlicht by providing at least one fiducial having a different shape to thereby obtain a substrate having fiducials of differing

shape (e.g. a different shape in each corner) to further facilitate identification of the bioagent on the substrate by detecting the shape and position of the most proximal fiducial.

Regarding Claim 7, Augenlicht teach the similar array comprising at least three non-linear fiducials wherein said fiducial is a defined edge of said substrate (Fig. 1).

Regarding Claim 8, Walt et al. teach the array wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach a fiducial bead. However, Augenlicht teaches the similar array comprising fiducials wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of bioagents of interest by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify substrate comprising random distributed beads of Walt et al. to include fiducial beads as a markers for the expected benefits of fiducial markers as taught by Augenlicht i.e. the markers facilitate analysis and identification of bioagents by their position relative to the fiducial (Column 7, lines 33-35).

Regarding Claim 9, Walt et al. teach the array wherein said bioactive agents are nucleic acids (Column 10, lines 4-17).

Regarding Claim 10, Walt et al. teach the array wherein said bioactive agents are proteins (Column 9, lines 38-67).

Regarding Claim 18, Walt et al. teach method of making an array composition comprising: forming a substrate with a surface comprising individual sites; and distributing microspheres on said surface such that said individual sites contain microspheres wherein said microspheres comprise at least a first and a second subpopulation each comprising a bioactive agent (Column 8, lines 1-11) wherein said microspheres are distributed on said surface (Column 4, lines 4-14) but they do not teach incorporating at least one fiducial onto said surface. However, Augenlicht teaches a similar method of making an array composition comprising a providing substrate comprising individual sites; distributing bioactive agents on

said surface wherein said agents comprise at least a first and second population; and at least one fiducial (Column 7, lines 18-35) wherein bioagents are identified relative to the position of the fiducials (Column 8, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the surface of Walt et al. to further comprise at least on fiducial for the expected benefit of facilitating analysis and identification of the bioagents by their position relative to the fiducial as taught by Augenlicht (Column 7, lines 33-35).

Regarding Claim 19, Walt et al. teach the method wherein each subpopulation comprises an identifier binding ligand that will bind a decoder binding ligand such that the identification of the bioactive agent can be elucidated (Column 10, lines 37-60).

Regarding Claim 20, Walt et al. teach the method wherein each subpopulation comprises a unique optical signature such that the identification of the bioactive agent can be elucidated (Column 4, lines 9-14).

Regarding Claim 21, Walt et al. teach the method wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach a fiducial fiber. However, Augenlicht teaches the similar method comprising fiducials wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of bioagents of interest by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify substrate consisting of a fiber optic bundle of Walt et al. to include a fiducial fiber as a marker for the expected benefits of fiducial markers as taught by Augenlicht i.e. the markers facilitate analysis and identification of bioagents by their position relative to the fiducial (Column 7, lines 33-35).

Regarding Claim 22, Walt et al. teach the method wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach said array comprises at least three non-linear fiducials. However, Augenlicht teaches the similar method comprising at least three

non-linear fiducials (Fig. 1) wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of bioagents by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26).

Regarding Claim 23, Augenlicht teach the similar method comprising at least one fiducial wherein the position of the fiducial on the substrate facilitates analysis and identification of the bioagents by identifying their position relative to the fiducial (Column 7, lines 33-35) but they do not teach the fiducial has a different shape from the others. However, it would have been obvious to one skilled in the art to modify fiducials of Augenlicht by providing at least one fiducial having a different shape to thereby obtain a substrate having fiducials of differing shape (e.g. a different shape in each corner) to further facilitate identification of the bioagent on the substrate by detecting the shape and position of the most proximal fiducial.

Regarding Claim 24, Augenlicht teach the similar method comprising at least three non-linear fiducials wherein said fiducial is a defined edge of said substrate (Fig. 1).

Regarding Claim 25, Walt et al. teach the method wherein said substrate is a fiber optic bundle (Column 4, lines 4-6) but they do not teach a fiducial bead. However, Augenlicht teaches the similar method comprising fiducials wherein the fiducials function as markers to denote positions on the substrate and facilitate analysis and identification of bioagents of interest by identifying their position on the substrate relative to the fiducial (Column 8, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify substrate comprising random distributed beads of Walt et al. to include fiducial beads as a markers for the expected benefits of fiducial markers as taught by Augenlicht i.e. the markers facilitate analysis and identification of bioagents by their position relative to the fiducial (Column 7, lines 33-35).

Regarding Claim 26, Walt et al. teach the method wherein said bioactive agents are nucleic acids (Column 10, lines 4-17).

Regarding Claim 27, Walt et al. teach the method wherein said bioactive agents are proteins (Column 9, lines 38-67).

10. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (U.S. Patent No. 6,023,540, filed 14 March 1997) in view of Augenlicht, L. (U.S. Patent No. 4,981,783, filed 16 April 1986) and Chee et al. (U.S. Patent No. 5,795,716, issued 18 August 1998).

Regarding Claim 11, Walt et al. teach an array composition comprising: a substrate with a surface comprising discrete sites; and a population of microspheres comprising at least a first and a second subpopulation wherein each subpopulation comprises a bioactive agent (Column 8, lines 1-11) wherein said microspheres are distributed on said surface (Column 4, lines 4-14) and wherein the array is analyzed automatically using available software (Column 4, lines 20-27) but they do not teach the composition comprises at least one fiducial and a computer readable memory and computer codes. Chee et al. teach an array composition comprising a substrate with a surface comprising discrete sites and a population of bioactive agents (Column 3, lines 34-47) and further comprising computerized analysis using a computer readable memory comprising: a computer code that receives a first data image; and a computer code that registers said first data image (Claim 1). Additionally, Augenlicht teaches a similar array composition comprising a substrate comprising discrete sites; a population of bioactive agents comprising at least a first and second subpopulation wherein said agents are distributed on said surface; and at least one fiducial (Column 7, lines 18-35) wherein bioagents are identified relative to the position of the fiducials (Column 8, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the surface of Walt et al. to further comprise at least on fiducial for the expected benefit of facilitating analysis and identification of the bioagents by identifying their position on the

substrate relative to the fiducial as taught by Augenlicht (Column 7, lines 33-35). It would have been further obvious to one skilled in the art to modify the array compositions of Walt et al. and Augenlicht with the computer readable memory of Chee et al. to use said fiducial to position-specifically receive and register a first data image via the computer code for the expected benefit of computer aided improved analysis of bioagents as taught by Chee et al. (Column 1, lines 55-67).

Regarding Claim 12, Chee et al. teach the computer readable memory further comprises a computer code that receives a second data image; a computer code that registers said second data image; and a computer code that compares said first and second data image (Claim 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further modify the array compositions of Walt et al. and Augenlicht with the computer readable memory further comprising a computer code that receives and registers a second data image and compares the first and second data images for the expected benefit of allowing image analysis and statistical analysis of multiple datafiles simultaneously as taught by Chee et al. (Column 22, lines 23-32).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
April 18, 2001

W. Gary Jones
Supervisory Patent Examiner
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4/19/01